PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY To: NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND GLAXOSMITHKLINE Corporate Intellectual Property THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION Attn. McKinnell, Denise CN925.1 980 Great West Road Brentford, Middlesex UNITED KINGDOM thKline ENTEC (PCT Rule 44.1) £ <u>o-</u> 99 Date of mailing ø (day/month/year) 30/05/2005 00.0 α Applicant's or agent's file reference SOX 000 3 FOR FURTHER ACTION See paragraphs 1 and 4 below DMK/PB60734 至 International application No. international filing date Ö **CCE** (day/month/year) 10/02/2005 PCT/EP2005/001441 Applicant GLAXO GROUP LIMITED The applicant is hereby notified that the international search report and the written opinion of the international Searching Authority have been established and are transmitted herewith. Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international Application (see Rule 46): The time limit for illing such amendments is normally 2 months from the date of transmittal of the international Search Report; however, for more details, see the notes on the accompanying sheet. International Bureau of WIPO, 34 chemin des Colombettes Where? Directly to the 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 740.14.35 For more detailed instructions, see the notes on the accompanying sheet. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that: the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices. no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made, Shortly after the expiration of 18 months from the priority date, the international application will be published by the international Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the international Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication. The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an International preliminary examination (epon has been or is to be established. These comments would also be made available to the public but not before the explration of 30 months from the priority date. Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. in respect of other designated Offices, the time limit of 30 months (or later) will apply even it no demand is filed within 19 See the Americ Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site. Name and mailing address of the International Searching Authority Authorized officer European Patent Office, P.B. 5818 Patentiaan 2 NL-2280 HV Rijewijk Tel. (431-70) \$40-2040, Tx. 31 651 epo nl. Fax: (431-70) \$40-3016 Natalia Morancho Alcaine

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basis instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty, in case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary exemination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional projection or has another meason for amending the claims before international policition. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further emended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 4).

When?

Within 2 months from the date of transmittal of the international search report of 15 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Figlic 45.1).

Where not to file the uniondments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 45.2).

Where a demand for international preliminary examination has been is filed, see below.

How?

Either by carrotting one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims eppearing on a replacement aftest must be numbered in Arabic numerals. Where a claim is cancelled, no tersumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the tanguage in which the international application is to be published.

What documents must may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The lefter must be in English or French; at the choice of the applicant. However, if the language of the international application is English; the letter must be in English; if the language of the international application is French, the letter must be in French.

Notes to Form PCY/ISA/220 (first sheet) (January 1994)

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- the claim is unchanged;
- (ii) the citim is carcelled;
- (iii) the claim is now;
- (iv) The olaim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples (Businets the manner in which amendments must be explained in the accompanying letter:

- (Where originally there were 48 claims and after amendment of some claims there are 51):
 "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- Where originally there were 15 claims and after amendment of all claims there are 11): *Claims 1 to 15 replaced by amended claims 1 to 11.*
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new plaims);
 "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 edded," or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of smer/diments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rute 48.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It wast he in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended, it must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of stations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the international Europau, also file a copy of such amendments with the international Prefiminary Examining Authority (see Palle 62:2(a), first sentence).

Consequence with regard to translation of the International application for entry into the national physic

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Officer, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PGT Article 18 and Rules 43 and 44)

	(o Miles 19 and total 40		
Applicant's or agent's file reference DMK/PB60734	FOR FURTHER ACTION	see Form PCT. as well as, where applica	
International application No.	international filing date (day/mor	ith/year) (Earliest) Priori	ity Date (day/month/year)
PCT/EP2005/001441	10/02/2009	5	12/02/2004
Applicant			
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GLAXO GROUP LIMITED			
This international Search Report has be according to Article 18. A copy is being			millied to the applicant
This international Search Report consis	ils of a lotal of <u>4</u> s	heets.	
It is also accompanied t	by a copy of each prior an document	cited in this report.	,
1. Basis of the report	<u> </u>		
a. With regard to the language, the language in which it was filed, u	ne înternational search was carried or untess otherwise indicated under this	ut on the basis of the internation item.	onal application in the
The internations this Authority (F	al search was camed out on the basi Rule 23.1(b)).	s of a translation of the interna	ational application turnished to
b. With regard to any nucl	leotide and/or amino acid sequenç	e disclosed in the internationa	ai application, see Box No. I.
2. X Certain claims were fo	ound unsearchable (See Box II),		
3. Unity of Invention is is	acking (see Box III).		
4. With regard to the 18ths,			
the rext is approved as:	submitted by the applicant.		
X the text has been estab	lished by this Authority to read as fol-	lows:	
2-METHOXY-5-(5-TRIFLU	Joromethyl-Tetrazol-1-	YL-BENZYL) - 25-PHE	VYL-PIPERIDIN-3S-YL) -
AMING FOR THE TREATME	INT OF SOCIAL PHOBIA		
			•
			i
5. With regard to the abstract,			
 	Submitted by the applicant.		I
the text has been estab	lished, according to Rule 38.2(b), by	this Authority as it appears in	Box No. IV, The applicant
may, within one month i	from the date of mailing of this interna-	ational search report, submit o	comments to this Authority.
6. With regard to the drawings,			
a. the figure of the drawings to be	published with the abstract is Figure	No	1
as suggested by	y the applicant.		
as selected by t	his Authority, because the applicant	feiled to suggest a figure.	1
	his Authority, because this figure bet	ler characterizes the invention	7-
b none of the figures is to	be published with the abstract,		

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP2005/001441

According to international Patent Classification (IPC) or to both national dessification and IPC B. FIELOS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 'A61K Documentation searched other than minimum documentation to the extent that such documenta are included in the fields searched Sectionic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data	
B. FIELOS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 'A61K Documentation searched other than minimum documentation to the extent that such documenta are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used)	
Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used)	und IPC
IPC 7 A61K Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used)	
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)	
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	i, whore practical, search lerms used)
C. DOCUMENTS CONSIDERED TO SE RELEVANT	` <u></u>
Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim	passages Relevant to claim No
L,P, WO 2004/091617 A (GLAXO GROUP LIMITED; X MELOTTO, SERGIO) 28 October 2004 (2004-10-28) abstract page 7, line 32 table 1	
WO 99/24423 A (MERCK SHARP & DOHME LIMITED; ELLIOTT, MATTHEW, JASON) 20 May 1999 (1999-05-20) abstract page 8, Itne 28	1-7
Further documents and listed in the continuation of box C. X Patent family members are listed in annex.	Patent family members are listed in annex.
*Spedial categories of cited documents: 'A' document defining the general state of the an which is not considered to be of particular relevance. 'E' optier document but published on or after the international filing date or provity date and not in conflict with the application but considered to be of particular relevance; the claimed invertion invention. 'X' document of particular relevance; the claimed invertion cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone which is cited to establish the publication date of another cannot be considered to involve an inventive step when the document or particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such document is combined with one or more	or priority date and not in conflict with the application but clied to understand the principle or theory underlying the invention occurrent of particular relevance; the claimed invertion cannot be considered to involve an inventive step when the document is taken alone occurrent of particular relevance; the claimed invention cannot be considered to involve an inventive step when the occurrent is combined with one or many other such documents to orbitised with one or many other such documents, such combination being obvious to a person skilled in the art.
Date of the actual completion of the international search Posts of mailing of the international search report.	ale of mailing of the international search report.
18 May 2005 30/05/2005	30/05/2005
Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5816 Patentisan 2 NL — 2280 HV Figswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo ni. Fax: (+31-70) 340-3016 Giacobbe, S	•

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INTERNATIONAL SEARCH REPORT

International application No. PCT/EP2005/001441

Box (I	Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)
This inte	emational Search Report has not been established in respect of certain dalms under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, riamely:
	Although claims 2-7 are directed to a method of treatment of the human/animal body; the search has been carried out and based on the alleged effects of the compound/composition.
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:
з. 🗌	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box W	Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This inte	rmational Searching Authority found multiple inventions in this International application, as follows:
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. <u> </u>	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. 🗌	As only some of the required additional search fees were timely paid by the applicant, this international Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the Invention first mentioned in the claims, it is covered by dalms Nos,:
- Remark	on Protest The additional search fees were accompanied by the applicant's protest.
	No protest accompanied the payment of additional search tees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No PCT/EP2005/001441

Patent document cited in search report		Publication d ate		Patent family member(s)	Publication date
WO 2004091617	А	28-10-2004	MO MO MO	2004091615 A1 2004091616 A1 2004091617 A1 2004091624 A1	28-10-2004 28-10-2004 28-10-2004 28-10-2004
WO 9924423	A	20-05-1999	AU CA EP WO JP US	9755498 A 2309162 A1 1028957 A1 9924423 A1 2001522847 T 2002052504 A1	31-05-1999 20-05-1999 23-08-2000 20-05-1999 20-11-2001 02-05-2002